

Special 510(k) Summary:
Zero Profile Anterior Cervical Plate System, MAR 22 2007

Line Extension to the Stryker Spine Reflex™ Hybrid ACP System

Proprietary Name: Zero Profile Anterior Cervical Plate (ACP) System

Common Name: Anterior Cervical Plate System

Proposed Regulatory Class: Class II
Spinal Intervertebral Body Fixation Orthosis,
21 CFR 888.3060

Device Product Code: KWQ

Sponsor: Stryker Spine

For Information contact: Simona Voic
Regulatory Affairs Project Manager
Stryker Spine
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Date Summary Prepared: February 28, 2007

Predicate Device Reflex™ Hybrid ACP System (K062310, K040261)
Synthes Cervical Spine Locking Plate System
(K000536 and K000742)

Device Description

The Zero Profile ACP System includes anterior cervical plates in one-level and two-level configurations, and in lengths from 12mm to 42mm, depending on the configuration. The subject plates are intended for use with the predicate Reflex Hybrid™ ACP bone screws. The components of the Zero Profile ACP system are manufactured from Ti6Al4V alloy per ASTM F-136 and will be provided non-sterile.

Intended Use

The Zero Profile Anterior Cervical Plating (ACP) System is intended for anterior intervertebral screw fixation of the cervical spine at levels C2-T1. The system is indicated for temporary stabilization of the anterior spine during the development of cervical spine fusions in patients with the following indications:

- Degenerative Disc Disease (as defined by neck pain of discogenic origin with degeneration of the disc confirmed by patient history and radiographic studies)
- Trauma (including fractures)
- Tumors
- Deformities or curvatures (including kyphosis, lordosis, or scoliosis)
- Pseudarthrosis
- Failed previous fusion
- Decompression of the spinal cord following total or partial cervical vertebrectomy
- Spondylolisthesis
- Spinal stenosis

Summary of the Technological Characteristics

WARNING: This device is not approved or intended for screw attachment to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine. The intended use and materials of the subject anterior cervical plates are identical to those of the predicate anterior cervical plates. The new plates feature a lower profile design than the predicate Reflex Hybrid™ Anterior Cervical Plates, but are used with the predicate Reflex Hybrid™ ACP System screw.

Engineering analysis and performance testing verify that the subject device system is substantially equivalent in terms of performance characteristics to the predicate device systems.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Stryker Spine
c/o Ms. Simona Voic
Regulatory Affairs Project Manager
2 Pearl Court
Allendale, New Jersey 07401

MAR 22 2007

Re: K063430
Trade/Device Name: Zero Profile Anterior Cervical Plate System
Regulation Number: 21 CFR §888.3060
Regulation Name: Spinal Intervertebral Body Fixation Orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: November 10, 2006
Received: November 13, 2006

Dear Ms. Voic:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson". The signature is fluid and cursive, with the last name "Melkerson" being more prominent.

Mark N. Melkerson
Director
Division of General, Restorative and
Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K063430

Device Name: Zero Profile Anterior Cervical Plate System

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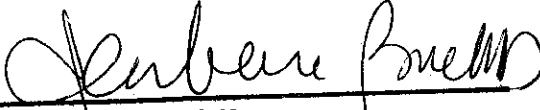
Prescription Use X
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

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